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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,562	07/08/2002	Charles V Clevenger	PENN-0798	7451

7590 05/18/2005

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EXAMINER	
ODELL, LINDSAY T	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,562	CLEVENGER ET AL.	
	Examiner	Art Unit	
	Lindsay Odell	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-6,9 and 10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *14 February 2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Application Status

1. This application is filed under 35 U.S.C 371, which is the national stage entry of PCT/US00/21789 filed on August 10, 2000. In response to the previous Office action, a written restriction requirement (mailed on October 20, 2004), Applicants filed a response received on February 22, 2005, in which a new listing of claims was submitted. Examiner notes that these claims are identical to the original PCT claims submitted on July 8, 2002 and are different from the amended PCT claims submitted on August 9, 2001 (see PTO-892). Claims 1-10, as amended in the response filed February 22, 2005, are pending in this instant Office action.

Restriction

2. The instant Office action contains a supplemental restriction requirement that better groups the instant claims; said action is the second supplemental restriction requirement. Said supplemental requirement is at the discretion of the Examiner (see M.P.E.P. § 802 and 37 C.F.R. § 1.142) and is deemed appropriate and necessary in view of the complex subject matter of the instant claims.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, drawn to a composition for modulating somatolactogenic function comprising cyclophilin B.

Group II, claim(s) 1-2, drawn to a composition for modulating somatolactogenic function comprising a mutant of cyclophilin B.

Group III, claim(s) 1-2, drawn to a composition for modulating somatolactogenic function comprising an inhibitor of the interaction of cyclophilin B with a somatolactogenic hormone.

Group IV, claim(s) 3-4, drawn to a method for modulating somatolactogenic function in an animal comprising administering cyclophilin B.

Group V, claim(s) 3 and 5-6, drawn to a method for modulating somatolactogenic function in an animal comprising administering a mutant of cyclophilin B.

Group VI, claim(s) 3 and 5-6 drawn to a method for modulating somatolactogenic function in an animal comprising administering an inhibitor of the interaction of cyclophilin B with a somatolactogenic hormone.

Group VII, claim(s) 7-8, drawn to a method for identifying test compounds as inhibitors of somatolactogenic functions comprising assessing the ability of test compound to inhibit the interaction of cyclophilin B with a somatolactogenic hormone.

Group VIII, claim(s) 9-10, drawn to a method for diagnosing diseases associated with abnormal somatolactogenic functions comprising obtaining a biological sample from a patient and comparing cyclophilin B levels in the patient with cyclophilin B levels of a normal individual.

3. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The first technical feature of Claim 1 is a composition comprising cyclophilin B and a pharmaceutically acceptable carrier; said feature is assigned to Group I. The technical feature of Group I is

not a special technical feature because it is anticipated by Bugli *et al.* (see PTO-892). Bugli *et al.* teach *Schistosoma mansoni* cyclophilin B in 20mM Tris-HCl, pH 7.8. (see page 341, column 2 and Table 2, page 344). In the broadest reasonable interpretation of the claims, the buffer taught by Bugli can be considered a pharmaceutically acceptable carrier. Thus, Bugli *et al.* have anticipated Group I and the technical feature of Group I is not a special technical feature. Without a special technical feature, Group I cannot share unity of invention with the other Groups.

Examiner notes that the products of Groups II-III do not share a technical feature with Group I because they have distinct structures and functions that characterize their technical features. The technical feature of Group II, a mutant of cyclophliin B, has a distinct amino acid sequence and functions as a mutant of cyclophilin B. Likewise, the technical feature of Group III, an inhibitor, has the structure of any organic molecule and functions to disrupt the interaction of cyclophilin B with a somatolactogenic hormone.

Lastly, the methods of Groups IV-VIII are of different categories of invention (methods as opposed to products) with respect to Group I. The methods of Groups IV-VIII do not share a special technical feature with Group I because Group I does not have a special technical feature; thus, Groups IV-VIII need not be grouped with Group I. Thus, the instant claims have been appropriately restricted according to lack of unity practice as the claims lack a common special technical feature, are of different categories of invention, and/or the products are not specifically adapted for use in the claimed methods.

Accordingly, Groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Election

4. Applicant's election with traverse of Group IV, claims 7-8, in the response to the previous office action, a written restriction requirement (mailed on October 20, 2004) is acknowledged. This office action includes a supplemental restriction requirement that changes the Groups compared to the written restriction requirement mailed on October 20, 2004. However, claims 7-8, elected to be examined by Applicant, remain together in Group VII. The Examiner acknowledges Applicant's election of claim 7-8; thus, to expedite prosecution, Group VII, claims 7-8 are examined herein.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined, selected from Groups I-VIII, even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

5. The instant application is granted the benefit of priority for the U.S. provisional Application No. 60/149752 filed on August 19, 1999 as requested in the declaration.

Information Disclosure Statement

6. The information disclosure statements filed on February 14, 2002 has been reviewed, and its references have been considered as shown by the Examiner's initials next to teach citation on the attached copy.

Compliance with Sequence Rules

7. The sequence listing, filed in computer readable form (CRF) and paper copy on February 14, 2002 has been received and entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "somatolactogenic hormone" is unclear as to the metes and bounds it imparts on the claimed subject matter. A definition for the term "somatolactogenic hormone" is not disclosed in the specification. In addition, the term "somatolactogenic hormone" is not clearly defined in the art with a single meaning. The Examiner finds three well-known members of the somatolactogen family in the art: prolactin, growth hormone and placental lactogen; however, it is unclear if Applicant means to claim only these three hormones, or if others are known in the art. Clarification is required.

Other Art for Comment

The following are cited to complete the record:

a) WO 9967288 A1 (Itoh *et al.*) teach cyclophlin B peptides as tumor antigens, antibodies to cyclophilin B peptides and the use of cyclophiln B peptides to treat and prevent tumors. Itoh *et al.* do not teach the interaction of cyclophilin B with hormones or disruption of an interaction of cyclophilin B with hormones.

b) Rycyzyn *et al.* (see PTO-892) review the role of cyclophilins in somatolactogenic action, and describe the identification of the interaction between cyclophilin B and prolactin and growth hormone.

Conclusion

9. Claims 7-8 are rejected for the reasons identified in the numbered sections of the Office action. Applicants must respond to the objections/rejections in each of the numbered sections in the Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lindsay Odell, Ph.D.
May 5, 2005